REMARKS

Claims 18-43 remain pending in the present application. Applicants respectfully traverse the rejections of the outstanding Office Action.

Rejections under 35 U.S.C. § 103(a)

Claims 18-43 stand rejected under 35 U.S.C. § 103(a) over Ayala in view of Shank (U.S. Patent No. 6,071,537), both in view of Anderson et al. (U.S. Patent No. 6,437,147). Applicants respectfully traverse.

The Examiner cites Ayala as allegedly teaching "the administration of zonisamide is effective in decreasing weight loss in patients," Shank allegedly teaches treating obesity with "compounds of formula I, including topiramate," and cites Andersen et al. as allegedly teaching "the administration of bupropion for the treatment of obesity." *Office Action* at 3. The Examiner states that it is "prima facie obvious to combine two compositions each of which is taught by the prior art to be useful for the same purpose, in order to form a third composition to be used for the very same purpose" and therefore "the skilled artisan would have been motivated to combine these well-known pharmaceuticals for the treatment of the very same ailment of obesity." *Office Action* at 4.

Applicants respectfully submit that Claims 18-43 do not recite the administration of bupropion, but rather are directed to methods of reducing weight by administering "a pharmaceutical composition comprising zonisamide." As stated in Applicants previous response, Claims 18-43 are directed to methods of reducing weight wherein "said weight loss is significant and sustained" (Claims 18-34), and wherein "the induction of weight loss is sustained during the dosing regimen" (Claims 35-43). Ayala does not teach or suggest methods of reducing weight wherein the weight loss is significant and sustained, or wherein the induction of weight loss is sustained during the dosing regimen, particularly in combination with the other recited limitations.

In addition, Applicants note that Ayala describes weight loss as an adverse effect of administering zonisamide to epileptic patients: "drug-related weight loss is considered to be an adverse event," and "in patients already below their ideal weights a further loss of 10% may be a problem." Other than discussing patients who are below their ideal body weight,

Ayala does not disclose or suggest any relationship between initial body weight (e.g., obesity) and weight loss caused by zonisamide in epileptic patients. Moreover, Ayala reports that there was no clear association between zonisamide dosage and weight loss. Ayala does not provide any evidence that the adverse effects of zonisamide are independent of the patients' epilepsy, and therefore there is no evidence that the reported weight loss is not caused or exacerbated by the epilepsy. The Examiner has not established any relationship between epileptic patients and obese patients that would lead one skilled in the art to expect that adverse events experienced by epileptic patients administered zonisamide would result in positive benefits for obese patients.

It is Applicants' understanding that NDA 20-789 for zonisamide states at pages 14-15:

> The prescriber should be aware that these figures, obtained when ZONEGRAN was added to concurrent AED therapy, cannot be used to predict the frequency of adverse events in the course of usual medical practice when patient characteristics and other factors may differ from those prevailing during clinical studies. Similarly, the cited frequencies cannot be directly compared with figures obtained from other clinical investigations involving different treatments, uses or investigators. An inspection of these frequencies, however, does provide the prescriber with one basis by which to estimate the relative contribution of drug and non-drug factors to the adverse event incidences in the population studied. *See Response under 37 CFR § 1.111, filed May 3, 2006, US Patent Application No. 10/429,474* at 3 (emphasis added, original emphasis removed).

As indicated by this passage, one skilled in the art would appreciate that adverse events are considered in view of the treatment being investigated (i.e., epilepsy) and in view of the patient population studied (i.e., epileptic patients). One skilled in the art would recognize that the adverse events are not used to predict how/whether the adverse events will occur for other treatments (e.g., obesity) in other patient populations (i.e., obese patients). Epileptic patients and obese patients are clearly two distinct patient populations that experience significantly different symptoms and prognoses, and the diseases have significantly different etiologies.

Accordingly, Applicants respectfully request withdrawal of the rejection of Claims 18-43 under § 103(a) over Ayala in view of Shank, both in view of Anderson et al.

Claims 18-43 also stand rejected under 35 U.S.C. § 103(a) over Coffin et al. (U.S. Pub. No. 2001/0025038). Applicants respectfully traverse.

Coffin et al. allegedly teaches, "a method for reducing cravings to food or an addictive substance with administration of bupropion and zonisamide." *Office Action* at 4. The Examiner states that Coffin provides the necessary motivation and guidance to treat obesity or reduce weight gain by reducing cravings for food. *Office Action* at 4-5. The Examiner argues that Coffin "inherently teaches of the single administration of zonisamide for the very same method of reducing food cravings in mammals" in its disclosure of the combined administration of bupropion and zonisamide. *Office Action* at 5.

Applicants respectfully submit that the disclosure of a combination of bupropion and zonisamide for the treatment of food cravings does not disclose the administration of compositions containing zonisamide as a method of reducing weight in an overweight subject or treating eating disorders in a subject in need of such treatment. Coffin et al. does not disclose, nor teach or suggest the administration of "a pharmaceutical composition comprising zonisamide" for "reducing weight in an overweight subject," as recited in Claims 18-43, let alone methods wherein "weight loss is significant and sustained" (Claims 18-34) or "the induction of weight loss is sustained during the dosing regimen" (Claims 35-43), particularly in combination with the other recited limitations.

Accordingly, Applicants respectfully request withdrawal of the rejection of Claims 18-43 under § 103(a) over Coffin et al.

Obviousness-type double patenting rejections

Applicants respectfully traverse the obviousness-type double patenting rejections set forth in the Office Action, but will consider filing a terminal disclaimer to obviate these rejections. Applicant would prefer to submit any such terminal disclaimers when the application is otherwise in condition for allowance, to avoid incurring the cost of submitting the terminal disclaimer until such time as it becomes necessary. A terminal disclaimer submitted in this application is not an admission of the propriety of the rejection. *See* M.P.E.P. § 804.02; *see also Quad Environmental Technologies Corp. v. Union Sanitary District*, 946 F.2d 870 (Fed. Cir. 1991) (noting that "the filing of a terminal disclaimer simply

serves the statutory function of removing the rejection of double patenting, and raises neither presumption nor estoppel on the merits of the rejection.").

CONCLUSION

In view of the above, Applicants respectfully maintain that claims are patentable and request that they be passed to issue. Applicants invite the Examiner to call the undersigned if any remaining issues may be resolved by telephone.

Please charge any additional fees, including any fees for additional extension of time, or credit overpayment to Deposit Account No. 11-1410.

Respectfully submitted,

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Dated: 10/17/2006

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